

# Arent Fox

**Stanley H. Abramson**  
Attorney  
202.857.8935 DIRECT  
202.857.6395 FAX  
Abramson.stanley@arentfox.com

December 23, 2009

## VIA FEDEX AND ELECTRONIC MAIL

Robert G. Perlis, Esq.  
Assistant General Counsel  
Office of General Counsel  
Mail Code: 2333A  
USEPA Headquarters  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Mr. Daniel Kenny  
Chief, Herbicide Branch  
Office of Pesticide Programs  
Mail Code: 7505P  
USEPA Headquarters  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Re: Petition to Deny Registration of Agrilon International, LLC's Agrilon Glyphosate Technical and Agrilon Glyphosate 62% MUP Herbicides

Dear Messrs. Perlis and Kenny:

This firm represents Monsanto Company ("Monsanto") as the original registrant and the primary data submitter for the herbicide active ingredient glyphosate. Monsanto seeks to protect its property interest in the extensive data that it has developed in support of its glyphosate registrations including studies that support the over-the-top uses of glyphosate on glyphosate-tolerant crops.

Agrilon International, LLC ("Agrilon") has applied for technical and manufacturing use registrations for herbicides referred to as Agrilon Glyphosate Technical and Agrilon Glyphosate 62% MUP, respectively, containing the active ingredient glyphosate. Agrilon applied for these registrations in reliance on Monsanto's data without Monsanto's authorization and without making an offer to pay that complies with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and implementing regulations of the U.S. Environmental Protection Agency ("EPA" or "Agency"). Moreover, in submitting its applications to EPA, Agrilon has failed to list all data requirements applicable to its products and/or failed to demonstrate compliance with all applicable data requirements. Finally, Agrilon has failed to participate in an agreed upon procedure for reaching an agreement on the amount and terms of compensation as required under FIFRA and EPA implementing regulations. In so doing,

Arent Fox

Agrilon has deprived Monsanto of the rights accorded to it under federal law. Accordingly the applications of Agrilon should be denied.

A Petition to Deny is enclosed for your consideration. Monsanto is providing a copy of this Petition to Agrilon by Certified Mail - Return Receipt Requested.

Thank you for your prompt consideration of this matter.

Sincerely,



Stanley H. Abramson  
Counsel for Monsanto Company

Enclosure

cc: Ms. Janelle Kay  
Pyxis Regulatory Consulting, Inc.  
Agent for Agrilon International, LLC  
4110 136 St. NW  
Gig Harbor, WA 98332

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE ADMINISTRATOR

PETITION OF MONSANTO COMPANY TO DENY  
THE REGISTRATION OF AGRILON INTERNATIONAL, LLC'S AGRILON GLYPHOSATE  
TECHNICAL AND AGRILON GLYPHOSATE 62% MUP HERBICIDES

Submitted by:

Mary M. Shaffer, Esq.  
Environmental and Regulatory Law Lead  
Crop Protection Division  
Monsanto Company  
800 North Lindbergh Boulevard  
Mail Code B2SG  
St. Louis, MO 63167

Stanley H. Abramson, Esq.  
Rachel G. Lattimore, Esq.  
Eric S. Baxter, Esq.  
Arent Fox LLP  
1050 Connecticut Avenue, NW  
Washington, DC 20036-5339  
202-857-6000

Counsel for Monsanto Company

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE ADMINISTRATOR

PETITION OF MONSANTO COMPANY TO DENY  
THE REGISTRATION OF AGRILON INTERNATIONAL, LLC'S AGRILON GLYPHOSATE  
TECHNICAL AND AGRILON GLYPHOSATE 62% MUP HERBICIDES

1. INTRODUCTION

Monsanto Company ("Monsanto") submits this petition pursuant to the data use and compensation provisions of Section 3(c)(1)(F) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136(c)(1)(F), Section 408(i)(1) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a(i)(1), and the Environmental Protection Agency ("EPA" or "Agency") Procedures to Ensure Protection of Data Submitters' Rights, 40 C.F.R. pt. 152, subpt. E. Monsanto is the original registrant and the primary data submitter for the herbicide active ingredient glyphosate. Monsanto seeks to protect its property interest in the extensive data that it has developed in support of its glyphosate registrations including studies that support the over-the-top uses of glyphosate on glyphosate-tolerant crops.

Agrilon International, LLC ("Agrilon") has applied for technical and manufacturing use registrations for herbicides referred to as Agrilon Glyphosate Technical and Agrilon Glyphosate 62% MUP, respectively, containing the active ingredient glyphosate. Agrilon applied for these registrations in reliance on Monsanto's data without Monsanto's authorization and without making an offer to pay that complies with the provisions of FIFRA and EPA implementing regulations. Moreover, in submitting its applications to EPA, Agrilon has failed to list all data requirements applicable to its products and/or failed to demonstrate compliance with all applicable data requirements. Finally, Agrilon has failed to participate in an agreed upon procedure for reaching an agreement on the amount and terms of compensation as required under

FIFRA and EPA implementing regulations. In so doing, Agrilon has deprived Monsanto of the rights accorded to it under FIFRA and FFDCA. Accordingly the applications of Agrilon should be denied.

## II. DISCUSSION

Monsanto has received two letters from Agrilon purporting to provide the data use and compensation notice required by FIFRA and EPA implementing regulations – neither of the Agrilon letters succeed. The first letter, dated August 27, 2009, and received on September 3, 2009, indicated Agrilon's intent to apply for a technical use registration for an herbicide referred to as Agrilon Glyphosate Technical. The second letter, dated September 11, 2009, and received on September 21, 2009, indicated Agrilon's intent to apply for a manufacturing use registration for an herbicide referred to as Agrilon Glyphosate 62% MUP. The letters stated that the herbicides contain the active ingredient glyphosate, expressed Agrilon's intent to rely on data originally submitted to EPA by Monsanto in support of Monsanto's glyphosate registrations, offered to pay compensation to the extent required by FIFRA section 3(c)(1)(F), and offered to commence negotiations to determine the amount and terms of compensation, if any, due for the studies cited in Agrilon's applications. Agrilon's letters are attached as Exhibits 1 and 2. Monsanto responded to Agrilon's letters on October 13, 2009 (attached as Exhibit 3).

### Failure to Make a Valid Offer to Pay

In the absence of authorization from Monsanto, FIFRA provides that EPA may consider Monsanto's data in support of Agrilon's application "only if the applicant has made an offer to compensate the original data submitter." 7 U.S.C. § 136(c)(1)(F)(iii). Neither of the Agrilon letters contains a proper offer to pay, nor has Monsanto authorized the use of its data by Agrilon. Accordingly, both of Agrilon's applications for registration of glyphosate products should be

denied because it has “cited a study originally submitted by the petitioner, without the required authorization or offer to pay.” 40 C.F.R. 152.80, 152.99(a)(2)(vi).

Agrilon’s letters fail to meet the minimum requirements of FIFRA and the EPA’s data compensation regulations. Those regulations require Agrilon to certify that it has furnished to the original data submitter “[a]n offer to pay the person compensation to the extent required by FIFRA” section 3(c)(1)(F). 40 C.F.R. 152.93(b)(2)(iii), 152.95(b)(2)(iii). Agrilon’s letter dated August 27, 2009, for Agrilon Glyphosate Teehcnical and Agrilon’s letter dated September 11, 2009, for Agrilon Glyphosate 62% MUP attempt to limit the company’s offers to pay by making the offers “contingent on approval of the application.” In point of fact, FIFRA section 3(c)(1)(F) and the implementing EPA regulations consistently and repeatedly refer to the data compensation obligations of “the applicant” and nowhere do the statute or EPA regulations suggest that the applicant can avoid its obligation to negotiate an agreement with the original data submitter or, having reached an agreement, comply with its terms until such time as the applicant’s registration has been granted. To the contrary, “[t]he terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration.” 7 U.S.C. § 136(c)(1)(F)(iii) (emphasis supplied). If EPA determines “that an applicant has failed to participate in a procedure for reaching an agreement ... or failed to comply with the terms of an agreement”, the Agency “shall deny the application or cancel the registration ... .” *Id.* (emphasis supplied).

#### Failure to List All Applicable Data Requirements and/or Demonstrate Compliance with All Applicable Data Requirements

In submitting its applications to EPA, Agrilon has failed to list all data requirements applicable to its products and/or failed to demonstrate compliance with all applicable data requirements. Agrilon has stated that its applications use a combination of the selective method

of data citation, 40 C.F.R. 152.93, and the selective cite-all method, 40 C.F.R. 152.95. These methods of data citation require the applicant to identify the specific data requirements involved and the studies for which the offer to pay is made in the case of the selective method, 40 CFR 152.93(b)(2)(ii), and the specific data requirements for which the offer to pay for data is being made in the case of selective cite-all, 40 C.F.R. 152.95(b)(2)(ii). Agrilon's letters to Monsanto fail under both methods. For example, Agrilon has failed to identify the following key data requirements as identified by EPA itself in the 1993 Glyphosate Reregistration Eligibility Decision: 850.2100 (71-1): Avian Oral Toxicity, 850.2200 (71-2): Avian Dietary Toxicity, 850.1075 (72-1): Freshwater Fish Toxicity, 850.1010 (72-2): Acute Toxicity Freshwater Invertebrates, 870.3100 (82-1): 90-Day Oral – Rodent, 870.3800 (83-3): Reproduction and Fertility Effects, 870.5395 (84-2): In Vivo Cytogenetics, and 850.3020 (141-1): Honey Bee Acute Contact. Accordingly both of Agrilon's applications for registration of glyphosate products should be denied because Agrilon "has failed to list a data requirement applicable to [its] product, or has failed to demonstrate compliance with all applicable data requirements." 40 C.F.R. 152.80, 152.99(a)(2)(i).

#### Failure to Commence Negotiations

FIFRA also requires that an applicant for registration that relies on data submitted by an original data submitter must "participate in a procedure for reaching an agreement" on the amount and terms of compensation. 7 U.S.C. § 136(c)(1)(F)(iii). Monsanto responded to Agrilon's letters on October 13, 2009, accepted Agrilon's offers to enter into negotiations and requested Agrilon to enter into a Mutual Confidentiality Agreement to facilitate negotiations leading to a compensation agreement. Monsanto also advised Agrilon's agent of her client's obligations by letter of October 26, 2009. To date, Agrilon has not signed a Mutual

Confidentiality Agreement or attempted to pursue a timely negotiated settlement of Monsanto's data compensation claims. Indeed Agrilon appears to be taking the position that it has no obligation to negotiate with Monsanto until such time as Agrilon obtains a registration from EPA in reliance on Monsanto's data, a position contrary to that set forth in the statute and regulations discussed under the offer-to-pay requirements, *supra*.

Agrilon's refusal to "participate in a procedure for reaching an agreement" on the amount and terms of compensation is in direct violation of FIFRA section 3(c)(1)(F)(iii). If notwithstanding the limitations noted above with regard to Agrilon's offers to pay, EPA concludes that those offers are valid, then both of Agrilon's applications for registration of glyphosate products should be denied because Agrilon "has failed to participate in an agreed-upon procedure for reaching an agreement on the amounts and terms of compensation." 40 C.F.R. 152.80, 152.99(a)(1)(i).

### III. CONCLUSION

For the foregoing reasons, Monsanto respectfully requests that EPA deny Agrilon's applications to register its Agrilon Glyphosate Technical and Agrilon Glyphosate 62% MUP herbicides. The Agency's expeditious consideration of this petition will be greatly appreciated.

Respectfully submitted:

Mary M. Shaffer, Esq.  
Environmental and Regulatory Law Lead  
Crop Protection Division  
Monsanto Company  
800 North Lindbergh Boulevard  
Mail Code B2SG  
St. Louis, MO 63167



Stanley H. Abramson, Esq.  
Rachel G. Lattimore, Esq.



Eric S. Baxter, Esq.  
Arent Fox LLP  
1050 Connecticut Avenue, NW  
Washington, DC 20036-5339  
202-857-6000

Counsel for Monsanto Company

December 23, 2009

PYXIS REGULATORY CONSULTING, INC.

4110 136 St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

August 27, 2009

RECEIVED

VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED  
7008 1140 0000 2706 5940

SEP - 3 2009

Monsanto Company  
Agent for: Monsanto Company  
1300 I Street NW, Suite 450 East  
Washington, DC 20005

RE: Glyphosate Acid Offer-to-Pay

To Whom It May Concern:

Agrilon International, LLC is applying for registration of a technical product containing glyphosate acid (Chemical Code 417300) as the active ingredient under the product name "Agrilon Glyphosate Technical". Agrilon International, LLC is using the selective method of data support (40 C.F.R. §§ 152.90 - 152.96). For many guideline requirements, Agrilon International, LLC's application uses the "cite-all within selective" method (40 C.F.R. § 152.95) of support. Attachment 1 lists the guidelines for which Agrilon International, LLC is using the cite-all under selective method. Attachment 2 provides the specific studies cited in Agrilon International, LLC application under 40 C.F.R. § 152.93.

Please note that, in accordance with 40 C.F.R. § 152.93(b)(3), Agrilon International, LLC is not offering to pay for studies originally submitted to the EPA on or before the date that is 15 years before the date of Agrilon International, LLC's application for registration of the above-mentioned product. In accordance with Section 3(c)(1)(F) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, this letter constitutes Agrilon International, LLC's:

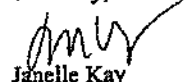
- 1) notification of its intent to apply for registration as required per 40 CFR § 152.93(b)(2)(i);
- 2) offer to pay compensation to the extent required by FIFRA section 3(c)(1)(F) contingent on approval of the application for data falling within the guideline requirements provided in Attachment 1 and for data cited in Attachment 2, provided that your company is identified as the "original data submitter", and
- 3) offer to commence negotiations to determine which data are subject to the compensation regulations of FIFRA, and the amount and terms of compensation, if any, due.

If you are aware if any studies listed in Attachment 2 do not satisfy applicable data requirements, please advise us within the next 60 days. Please also advise us whether you have submitted a replacement study to satisfy the applicable data requirement and, if so, the guideline number, study title, and MRID number of each such replacement study. We reserve the right to revise this offer to pay upon receiving this information from you.

If any of the studies listed in Attachment 2 do not satisfy the applicable data requirement and you have not submitted acceptable replacement study(ies), we request that you notify us that a data gap exists. Unless we hear from you, we will understand that there are no outstanding data requirements and Agrilon International, LLC will not claim a data gap for any data requirements.

Thank you very much for your cooperation.

Sincerely,



Janelle Kay  
Agent for Agrilon International, LLC

Attachments

### Attachment 1. Agrilon International LLC Agrilon Glyphosate Technical Offer-to-Pay

Guideline No.	Guideline Title
850.2300 (71-4)	Avian Reproduction
850.2400 (71-3)	Wild Mammal Toxicity
850.1300 (72-4)	Aquatic Invertebrate Life Cycle
850.1500 (72-5)	Fish Life Cycle
850.1710, 850.1730, 850.1850 (165-4)	Aquatic Organisms Bioavailability, Biomagnification, Toxicity
835.6200 (164-2)	Aquatic (Sediment) Field Dissipation Study
835.6300 (164-3)	Forestry Field Dissipation Study
860.1300 (171-4(b))	Nature of the Residue in Livestock
860.1400 (171-4(f))	Nature and Magnitude of the Residue in Drinking and Irrigation Water
860.1400 (171-4(g))	Magnitude of the Residue in Fish
860.1400 (171-4(h), 165-3)	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water
860.1480 (171-4(j))	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Root and Tuber Vegetables, excluding Roundup Ready
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Bulb Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Leafy Vegetables (except Brassica)
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Brassica Leafy Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Fruiting Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Cucurbit Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Citrus Fruits
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Pome Fruits
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Stone Fruits
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Small Fruits and Berries
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Tree Nuts
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Asparagus
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Avocado
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Bananas
860.1500 (171-4(k))	Magnitude of the Residue in Plants: Tropical Fruits (excludes pineapples)
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Coconut
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Coffee Beans
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Okra
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Olives
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Peanuts
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Sugarcane
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Herbs
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Vine Crops
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Roundup Ready alfalfa
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Roundup Ready canola
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Fruiting Vegetables
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Citrus Fruits
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Pome Fruits
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Stone Fruits
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Small Fruits and Berries
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Vine Crops
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Cotton, excluding Roundup Ready

Guideline No.	Guideline Title
860.1520 (171-4(I))	Magnitude of Residue in Processed Food/Feed – Olives
860.1520 (171-4(I))	Magnitude of Residue in Processed Food/Feed – Peanuts
860.1520 (171-4(I))	Magnitude of Residue in Processed Food/Feed – Sugarcane
860.1520 (171-4(I))	Magnitude of Residue in Processed Food/Feed – Roundup Ready canola
860.1850 (165-1)	Confined Crop Rotation Study
870.1100	Acute Oral Toxicity: Rat
870.1200	Acute Dermal Toxicity: Rat
870.2400	Primary Eye Irritation: Rabbit
870.2500	Primary Dermal Irritation
870.2600	Dermal Sensitization
870.4200	Carcinogenicity
201-1	Droplet Size Spectrum
202-1	Droplet Size Spectrum

**Attachment 2. Agrilon International LLC Agrilon Glyphosate Technical Offer-to-Pay**

43330601
43571801
43655701
43655702
43712701
43712702
44279301
44331601
44531301
44541201
44646601
45066901
45899101

PYXIS REGULATORY CONSULTING, INC.

4110 136 St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

September 11, 2009

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED  
7008 1140 0000 2706 6886

RECEIVED

SEP 21 2009

Monsanto Company  
Agent for: Monsanto Company  
1300 I Street NW, Suite 450 East  
Washington, DC 20005

RE: Glyphosate 62% MUP Offer-to-Pay

To Whom It May Concern:

Agrilon International, LLC is applying for registration of a manufacturing use product containing glyphosate in the form of the isopropylamine salt (Chemical Code 103601) as the active ingredient under the product name "Agrilon Glyphosate 62% MUP". Agrilon International, LLC is using the selective method of data support (40 C.F.R. §§ 152.90 - 152.96). For many guideline requirements, Agrilon International, LLC's application uses the "cite-all within selective" method (40 C.F.R. § 152.95) of support. Attachment 1 lists the guidelines for which Agrilon International, LLC is using the cite-all under selective method. Attachment 2 provides the specific studies cited in Agrilon International, LLC application under 40 C.F.R. § 152.93.

Please note that, in accordance with 40 C.F.R. § 152.93(b)(3), Agrilon International, LLC is not offering to pay for studies originally submitted to the EPA on or before the date that is 15 years before the date of Agrilon International, LLC's application for registration of the above-mentioned product. In accordance with Section 3(c)(1)(F) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, this letter constitutes Agrilon International, LLC's:

- 1) notification of its intent to apply for registration as required per 40 CFR § 152.93(b)(2)(i);
- 2) offer to pay compensation to the extent required by FIFRA section 3(c)(1)(F) contingent on approval of the application for data falling within the guideline requirements provided in Attachment 1 and for data cited in Attachment 2, provided that your company is identified as the "original data submitter", and
- 3) offer to commence negotiations to determine which data are subject to the compensation regulations of FIFRA, and the amount and terms of compensation, if any, due.

If you are aware if any studies listed in Attachment 2 do not satisfy applicable data requirements, please advise us within the next 60 days. Please also advise us whether you have submitted a replacement study to satisfy the applicable data requirement and, if so, the guideline number, study title, and MRID number of each such replacement study. We reserve the right to revise this offer to pay upon receiving this information from you.

If any of the studies listed in Attachment 2 do not satisfy the applicable data requirement and you have not submitted acceptable replacement study(ies), we request that you notify us that a data gap exists. Unless we hear from you, we will understand that there are no outstanding data requirements and Agrilon International, LLC will not claim a data gap for any data requirements.

Thank you very much for your cooperation.

Sincerely,

  
Janelle Kay  
Agent for Agrilon International, LLC

Attachments

## Attachment 1. Agrilon International LLC Agrilon Glyphosate 62% MUP Offer-to-Pay

Guideline No.	Guideline Title
850.2300 (71-4)	Avian Reproduction
850.2400 (71-3)	Wild Mammal Toxicity
850.1300 (72-4)	Aquatic Invertebrate Life Cycle
850.1500 (72-5)	Fish Life Cycle
850.1710, 850.1730, 850.1850 (165-4)	Aquatic Organisms Bioavailability, Biomagnification, Toxicity
835.6200 (164-2)	Aquatic (Sediment) Field Dissipation Study
835.6300 (164-3)	Forestry Field Dissipation Study
860.1300 (171-4(b))	Nature of the Residue in Livestock
860.1400 (171-4(f))	Nature and Magnitude of the Residue in Drinking and Irrigation Water
860.1400 (171-4(g))	Magnitude of the Residue in Fish
860.1400 (171-4(h), 165-3)	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water
860.1480 (171-4(j))	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Root and Tuber Vegetables, excluding Roundup Ready
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Bulb Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Leafy Vegetables (except Brassica)
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Brassica Leafy Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Fruiting Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Cucurbit Vegetables
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Citrus Fruits
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Pome Fruits
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Stone Fruits
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Small Fruits and Berries
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Tree Nuts
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Asparagus
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Avocado
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Bananas
860.1500 (171-4(k))	Magnitude of the Residue in Plants: Tropical Fruits (excludes pineapples)
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Coconut
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Coffee Beans
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Okra
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Olives
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Peanuts
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Sugarcane
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Herbs
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Vine Crops
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Roundup Ready alfalfa
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Roundup Ready canola
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Fruiting Vegetables
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Citrus Fruits
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Pome Fruits
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Stone Fruits
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Small Fruits and Berries
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Vine Crops
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed - Cotton, excluding Roundup Ready

Guideline No.	Guideline Title
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed – Olives
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed – Peanuts
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed – Sugarcane
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed – Roundup Ready canola
860.1850 (165-1)	Confined Crop Rotation Study
870.1100	Acute Oral Toxicity: Rat
870.1200	Acute Dermal Toxicity: Rat
870.2400	Primary Eye Irritation: Rabbit
870.2500	Primary Dermal Irritation
870.2600	Dermal Sensitization
870.4200	Carcinogenicity
201-1	Droplet Size Spectrum
202-1	Droplet Size Spectrum



**Attachment 2. Agrilon International LLC Agrilon Glyphosate 62% MUP Offer-to-Pay**

43330601
43571801
43655701
43655702
43712701
43712702
44279301
44331601
44531301
44541201
44646601
45066901
45899101

MONSANTO  
*Food • Health • Hope*



For more information, please contact:  
Monsanto Regulatory Affairs  
300 North Zeeb Road  
Moline, Illinois 61704-3000

October 13, 2009

Agrilon International, LLC  
c/o Janelle Kay  
Pyxis Regulatory Consulting, Inc.  
4110 136 St. NW  
Gig Harbor, WA 98332

Dear Ms. Kay:

**Re: Offers to Pay from Agrilon International, LLC ("Agrilon")**

On September 3, 2009, Monsanto Company ("Monsanto") received an August 27, 2009 offer to pay letter notifying it of Agrilon's application under FIFRA for the registration of "Agrilon Glyphosate Technical," a product containing glyphosate as the active ingredient. Additionally, on September 18, 2009, Monsanto received a September 11, 2009 offer to pay letter notifying it of Agrilon's application under FIFRA for the registration of "Agrilon Glyphosate 62% MUP," also a product containing glyphosate as the active ingredient. The letters both indicated Agrilon's intent to apply for this registration using reference to data owned by Monsanto, and offered to pay compensation to Monsanto to the extent required by FIFRA § 3(c).

As you are aware, Monsanto is a manufacturer and basic registrant of glyphosate, and we believe we possess core regulatory data that is relevant to your application and is compensable under FIFRA. Accordingly, Monsanto accepts Agrilon's offer to enter into negotiations regarding compensation for Monsanto data relating to this product(s). We believe we are entitled to compensation for any Monsanto data that are used in consideration of your registration applications or any future amendments to said registrations. We accept no time limitation upon our data compensation rights, other than those specified by FIFRA, and remind you that, contrary to your letters, Agrilon's obligation to compensate Monsanto is triggered by its submittal of an application for a registration that relies on Monsanto's data, not upon Agrilon's receipt of a registration.

Prior to entry into negotiations, Monsanto will require execution of a confidentiality agreement with respect to the data subject to your request. A draft confidentiality agreement is included with this letter. We expect a response by November 2, 2009. Should resolution of your compensation obligations not be achieved by ninety days after Monsanto's receipt of your offer to pay (December 17, 2009), Monsanto reserves its right to initiate arbitration pursuant to 7 U.S.C. § 136a(c)(1)(F) of FIFRA.

Monsanto will also be closely evaluating Agrilon's offer to pay and registration application to determine compliance with applicable requirements under FIFRA. Should the offer to pay or application be deficient, Monsanto reserves its right to petition EPA to deny Agrilon's application or cancel any resulting registration.

If you would like to discuss this issue further, please contact me at 314-694-7149.

Sincerely,

Dean W. Hendrickson  
Global Glyphosate Business Lead, Non-Branded

## **MUTUAL CONFIDENTIALITY AGREEMENT**

This Mutual Confidentiality Agreement ("Agreement"), effective as of the last date executed below, is between the Monsanto Company ("Monsanto"), with offices at 800 North Lindbergh Boulevard, St. Louis, MO 63167, and Agrilon International, LLC ("Agrilon"), with offices at \_\_\_\_\_. Monsanto and Agrilon are referred to herein individually as a "Party" and together as the "Parties."

Monsanto and Agrilon are engaged in discussions regarding the potential settlement of certain claims asserted or to be asserted against Agrilon by Monsanto pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and/or the Federal Food Drug, and Cosmetic Act for compensation for use of Monsanto data in support of Agrilon's application(s) for new or amended registrations(s) of pesticide products containing the active ingredient glyphosate (the "Potential Settlement"). It is expected that, during such discussions, certain nonpublic, confidential or proprietary information relating, on the one hand, to Monsanto and its affiliates, its compensation claims, and pesticide products produced and/or distributed by same, and, on the other hand, to Agrilon and its affiliates, its defenses to Monsanto's claims, and pesticide products produced and/or distributed by same, may be disclosed by one Party to the other (referred to herein as "Confidential Information"). The content of the Parties' discussions, statements made and positions taken by a Party, any written and electronic communications, and other information that may be disclosed by either Party shall be regarded as "Confidential Information." The sole purpose of such discussion and disclosure of information is to negotiate the terms and amount of data compensation which may be owed by Agrilon to Monsanto for reliance on Monsanto's data to support Agrilon's glyphosate registrations with the United States Environmental Protection Agency and the Parties wish to preserve the confidentiality of the information and positions exchanged in the course of such negotiations.

The delivery by each Party of such Confidential Information after the date of this Agreement, whether written, electronic, oral or in any other form or format, will expressly be in consideration of, and contingent upon, the other Party's agreement as follows:

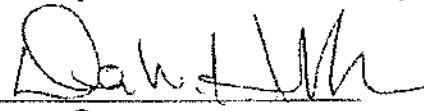
1. Subject to paragraph 4 of this Agreement, each Party will (a) use the other Party's Confidential Information solely for the purpose of evaluating the Potential Settlement and (b) keep such other Party's Confidential Information confidential and will not disclose such Confidential Information to any third party, except that each Party may disclose the other's Confidential Information or portions thereof to the directors, officers, employees, advisers and agents of such Party and its affiliates (collectively "Representatives") who need to know such information for the purpose of evaluating the Potential Settlement.
2. Each Party will inform its Representatives of the confidential nature of the Confidential Information and cause them to agree in writing to be bound by this agreement and will not disclose such Confidential Information to any Representatives other than those who have agreed to be bound by this agreement. Each Party agrees to be responsible for any breach of this agreement by its Representatives.

3. Prior to exchanging or disclosing Confidential Information in any written or electronic format, a Party shall mark such information prominently with the legend "Confidential Information" or "Subject to Confidentiality Agreement," however the omission of this legend shall not in any way diminish the protections under this Agreement for Confidential Information.
4. In the event that either Party or its Representatives become legally compelled to disclose any of the other's Confidential Information, such Party will provide the other Party with prompt written notice of such requirement and the opportunity to challenge it. Such notice shall be provided prior to such disclosure unless prior notice is not reasonably practicable, in which event such notice shall be provided promptly thereafter.
5. The term "Confidential Information" does not include any information which (a) at the time of disclosure or thereafter is generally available to and known by the public (other than as a result of disclosure in violation of the obligations under this Agreement), (b) was available to a Party on a nonconfidential basis from a source other than the other Party, provided that such information was not obtained by such source in a manner which would not comply with this Agreement, or (c) has been independently acquired or developed without violating any obligations under this Agreement.
6. If either Party shall so request, all of such requesting Party's Confidential Information, and all copies, analyses, compilations, excerpts, summaries, studies or other documents (regardless of by whom prepared) containing the requesting Party's Confidential Information, which are in the possession of the other Party or its Representatives (hereafter "receiving Party"), shall, at the election of the receiving Party, be (a) returned to the requesting Party or (b) destroyed by the receiving Party, and such destruction certified in writing by an officer of the receiving Party to the requesting Party.
7. Except as otherwise described in paragraphs 1, 4, and 14 of this Agreement, without the prior written consent of the other Party, a Party will not, and will direct its Representatives not to, disclose to any person any of the terms, conditions or other facts with respect to the Potential Settlement, including its status.
8. Each Party understands and acknowledges that the other Party is not making any representation or warranty, express or implied, as to the accuracy or completeness of the Confidential Information, and neither Party nor any of its Representatives will have any liability to the other Party, its Representatives or any person resulting from any use of the Confidential Information by such other Party, its Representatives or such other persons. Only those representations or warranties that are made in a definitive agreement with respect to the Potential Settlement, when, as, and if it is executed, and subject to such limitations and restrictions as may be specified in such agreement, shall have any legal effect.

9. Each Party agrees that, unless and until a definitive agreement with respect to the Potential Settlement has been executed and delivered, neither Party will be under any legal obligation of any kind whatsoever by virtue of this letter or otherwise, except for the matters specifically agreed to herein.
10. Each Party agrees that no right or license to or under intellectual property rights or other rights in and to Confidential Information is granted to the other Party under this agreement and that neither of the Parties is under any obligation to enter into any business arrangement or agreement with the other Party by virtue of this agreement or any disclosure hereunder.
11. This Agreement is without prejudice to the ability of the receiving party to seek in discovery in any pending or future litigation or arbitration, subject to the rules and protections in effect in such proceedings, the information provided to the receiving party hereunder, it being understood that in no event shall settlement positions taken, or offers of settlement made, by any Party under this Agreement be considered information legitimately subject to discovery. Additionally, all communications, whether verbal or written, relating to the Potential Settlement will be deemed to be in the nature of settlement discussions and shall not be admissible in any pending or future litigation or arbitration proceeding.
12. The terms set forth in this Agreement may not be amended or waived except by a separate writing signed by both Parties expressly amending or waiving this Agreement.
13. This Agreement shall not be assignable by either Party, by operation of law or otherwise, without the prior written consent of the other Party.
14. Without prejudice to any rights and remedies otherwise available to the Parties, each Party shall be entitled to equitable relief by way of specific performance, injunction or otherwise if the other Party or any of its Representatives breaches or threatens to breach any provisions of this Agreement. Notwithstanding the foregoing provisions, either Party may disclose Confidential Information to the decision-maker in a judicial or arbitral proceeding to enforce this Agreement or to resolve a dispute as to its validity or interpretation, provided that (1) the Party intending to disclose Confidential Information provides the other Party prior notice and a reasonable opportunity to oppose such disclosure; (2) the disclosure is reasonably necessary to the resolution of the dispute, and (3) the disclosing Party takes all reasonable efforts to ensure that the Confidential Information shall not be disclosed outside the proceeding.
15. This Agreement shall be governed by and construed in accordance with the laws of the state of Missouri, without regard to its principles of conflict of laws. Except as provided otherwise in this Agreement, the obligations hereunder shall expire ten (10) years after the date of this Agreement (which shall be deemed the date on which the last of the Parties signs this agreement).

16. Each Party executing this Agreement warrants that the individual signing this Agreement is an officer, a principal or an employee of the Party for which such individual signs, and has been granted or delegated all requisite power and authority to bind the Party for which such individual signs. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and assigns.

By: \_\_\_\_\_  
Agrilon International, LLC

By:   
Monsanto Company

Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

Name: Dean W. Hendrickson  
Title: Global Glyphosate Business Lead, Non-Branded  
Date: October 13, 2009